



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Los Angeles District
Pacific Region
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Irvine, CA 92612-2445

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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 41-04

June 29, 2004

RPM Total Vitality
18032 Lemon Drive, Suite C
Yorba Linda, CA 92886-3386

Dear Sir or Madam,

This letter is in reference to your firm's marketing and distribution of VITAL CHOICE Canthaxanthin capsules, 30 mg. Your Internet web site, www.rpmtotalvitality.com, promotes and markets this product with claims that establish its intended use to protect against sunburn, genetic damage, and cancer. Such labeling claims that indicate intended use for the prevention of disease cause this product to be a drug, as that term is defined at section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

Objectionable claims that appear on your web site include the following:

- "Canthaxanthin...might reduce a woman's risk for developing breast cancer..."
- "...Canthaxanthin might be an effective anti-carcinogenetic agent against the initiation of cancer..."
- "...carotenoids appear to be remarkably effective inhibitors of carcinogenesis (cancer) in humans."
- "The use of Canthaxanthin may decrease one's chances of getting skin cancer... by preventing sunburn damage to the skin."
- "...in animals, carotenoids act as ultraviolet light absorbers...protecting DNA from genetic damage."
- "This substantial increase in sunburn resistance...was presumably due to the addition of Orobzone (Canthaxanthin)..."
- "...his resistance to sunburn is dramatically improved. Recently, when he forgot to use sunblock on his nose, it received only minor sunburn compared to what would be expected..."
- "...protective effects are probably due to deactivation of excited oxygen..."

Because this drug is not generally recognized as safe and effective when used as labeled, it is a new drug under section 201(p) of the Act. A new drug may not be legally marketed in this country without an approved New Drug Application (NDA) [Section 505(a) of the Act].

Your "CANTHAXANTHIN INFORMATION" sheet that accompanies the product and your Internet web site also promote and market this product for coloring the skin. This entails an additional violation of the Act. The following information sheet and web site statements clearly establish the additional intended use of VITAL CHOICE Canthaxanthin capsules to alter the skin color to simulate a suntan rendering the product an adulterated cosmetic under section 601(e) of the Act:

Information Sheet:

- "HOW DOES CANTHAXANTHIN GIVE THE APPEARANCE OF A TAN?"
- "Canthaxanthin assimilates into the body and attaches to the subcutaneous layer of fat cells...through the translucency of skin, the darkened fat gives the appearance of a tan."
- "You can regulate the color by taking more or less capsules."
- "It takes about 3-4 weeks AFTER saturation before the 'tan' will be golden bronze."
- "Tanning beds will greatly enhance the darkening ability of the Canthaxanthin."

Web site:

- "I have a great tan all year because I take CANTHAXANTHIN"
- "Canthaxanthin was promoted as a safe tanning pill in Durk Pearson and Sandy Shaw's Life Extension."
- "...effect of Canthaxanthin is the turning of the fat layer... a bronze color. Since the skin is translucent, you appear to have—tadaaa—a tan!"
- "This Canthaxanthin...makes the skin look a much more natural reddish-brown color..."
- "You start taking four a day until you achieve the color you want..."
- "...colors the skin a beautiful natural-looking golden-copper tan when taken orally."
- "...canthaxanthin...ability to color human skin a golden-bronze color without UV exposure..."
- "The stuff works great! I got color with my first bottle."
- "I've been using Canthaxanthin and I'm brown as a berry!"
- "The results were astounding. In just three weeks my skin colour is dark brown."
- "My doctor told me to get this for my son who is very white and burns."
- "I have one of the best tans I've ever had."
- "I look dark all year round without going to the tanning beds with just two a day."
- "My friends have been envious of my tan...thanks to your Canthaxanthin."
- "I have blond hair and blue eyes, and I keep my color all year long."

The Act defines the term cosmetic at §201(i)(1) to mean articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance; and the term color additive at §201(t)(1)(B) to mean a material which, when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto. (emphases added)

From the above it is clear that VITAL CHOICE Canthaxanthin is also a cosmetic product, containing the color additive canthaxanthin, intended to impart color to the skin.

Color additives used in cosmetic products (or any product subject to FDA regulation) may be used only in accordance with color additive regulations that, among other things, specify the allowed product category and the conditions under which they may be safely used. There is no color additive regulation currently allowing for the use of canthaxanthin to impart color to the skin or, for that matter, for the use of canthaxanthin in a cosmetic product for any purpose.

Based on the above, the Canthaxanthin product you are currently marketing on your web site is considered an adulterated cosmetic in violation of §601(e) of the Act.

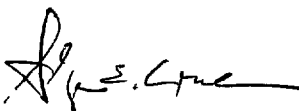
This letter is not intended to be an all inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, Los Angeles District Office, 19701 Fairchild Street, Irvine, CA 92612. If you have any questions regarding any issue in this letter, please contact MaryLynn Datoc, Compliance Officer at telephone number 949-608-4428.

Sincerely,



Alonza E. Cruse
Director, Los Angeles District

Cc: State of California
Department of Health Services
Food and Drug Branch
601 North 7th Street, MS-357
Sacramento, CA 94234-7320